PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Frederick M. Enright *et al.*

Serial No. 10/617,561

Filing Date: July 11, 2003

ATTENTION: Technology Center Director
Group 1600
(MPEP § 1002.02(c), par. 2)

For: Ligand / Lytic Peptide Compositions and Methods of Use (File 96A3.3 Enright)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO GROUP 1600 TECHNOLOGY CENTER DIRECTOR
UNDER 37 C.F.R. § 1.144
TO REVIEW FINAL RESTRICTION REQUIREMENT

On May 31, 2006, the Examiner mailed a five-way restriction requirement. On July 5, 2006 the Applicants responded, making a provisional election with traverse. The

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CERTIFICATE

I hereby certify that this Petition under 37 C.F.R. § 1.144 to Review Final Restriction Requirement, along with the accompanying check for $130 for the petition fee, are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450; Attention: Group Director, Group 1600 on September 12, 2006.

John H. Runnels
Registration No. 33,451
September 12, 2006

Examiner has now made the restriction requirement final, in an office action mailed August 18, 2006 (p. 2).

Applicants now petition the Technology Center Director to withdraw the restriction requirement.

This Petition is being filed timely under 37 C.F.R. § 1.144. From an abundance of caution, if any extension of time is required, please consider this paper a petition for the total extension of time required.

Enclosed is a check for $130 for the petition fee. In the event that this fee is incorrect, kindly refer to the general Deposit Account Authorization previously filed with the application.

I. BACKGROUND

The claimed inventions pertain to certain DNA sequences. The peptides that are encoded by these DNA sequences will specifically inhibit cells that are driven by specific ligand interactions, or that are dependent on specific ligand interactions. The DNA sequences and their encoded peptides may be used, for example, for long-term contraception or sterilization, or for inhibiting hormone-dependent tumors.

More specifically, the DNA sequences encode peptides that comprise a first domain and a second domain. The first domain of the encoded peptide comprises one of a specified list of hormones or their analogs (e.g., GnRH, LH, etc.). The second domain of the peptide comprises a lytic peptide.

Note that "lytic peptide" is an art-recognized term. It is not synonymous with "toxic peptide." Lytic peptides are a class of membrane-disrupting, amphipathic peptides, having

from 10 to 39 amino acid residues. For purposes of this Petition, it should suffice to note that lytic peptides are a well-defined category of membrane-acting peptides, having particular structural properties.

The encoded hormone / lytic peptide fusion peptide specifically inhibits cells with specific receptors for the hormone. The effect of administering the peptide to a patient may include, for example, induced sterility or long-term contraception, or the destruction of tumor cells.

The invention is well-suited for use to treat malignant or non-malignant tumors. The hormone, i.e., the ligand portion of the expressed peptide, is one for which the tumor cells express a corresponding receptor. Tumor cells are rapidly lysed by the fusion peptide. The fusion peptide is generally not antigenic, which means that a patient may receive repeated treatments without developing an adverse immune response.

II. THE RESTRICTION REQUIREMENT

The Examiner entered a five-way restriction requirement. The five Groups were characterized by the Examiner as follows:

Group I. Claim(s) 1-8, 11-14, 17, 127, 129, and 130 are drawn to a DNA sequence encoding a fusion peptide classified in class 536, subclass 23.1.

Group II. Claim(s) 31-41, 105-114, 120, 122 are drawn to a method for decreasing fertility in an animal classified in class 514, subclass 12.

Group III. Claim(s) 48, 59-70, 73-76, 79, 83, 86-87, 123, 124, 125, 126, and 128 are drawn to a method for killing or inhibiting the growth of a cell in a hormone-dependent or ligand-dependent tumor in a mammal classified in class 514, subclass 12.

Group IV. Claim(s) 116 and 118 are drawn to a method for selectively reducing the number of viable gonadotrophic cells in the pituitary of an animal classified in class 514, subclass 12.

Group V. Claims 131-133 are drawn to a vector wherein the DNA sequence is operatively linked to an acute-phase responsive promoter classified in class 435, subclass 320.1.

May 31, 2006 Restriction Requirement, p. 2. (Applicants do not necessarily adopt the Examiner's characterizations of the claims. The limitations of the individual claims will speak for themselves.)

The Applicants provisionally elected Group I and traversed the restriction requirement. (July 5, 2006 Response to Restriction Requirement) The requirement was recently made final by the Examiner. (August 18, 2006 Office Action, p. 2)

It is respectfully submitted that the restriction requirement should be withdrawn in its entirety, for the reasons given below.

III. THE EXAMINER HAS NOT DEMONSTRATED ANY SERIOUS BURDEN, AND THEREFORE MAY NOT REQUIRE RESTRICTION.

There are two separate criteria that must both be satisfied for a restriction requirement to be proper:

(1) The inventions must be independent or distinct as claimed;

and

(2) There must be a serious burden on the examiner if restriction is not required.

M.P.E.P. § 803, part I.

(1) The Examiner has not demonstrated that the inventions are independent or distinct. For this reason alone, the restriction requirement should be withdrawn. **(2)** Strictly in the alternative, even if the Examiner had shown that the inventions were distinct (and the Examiner has made no such showing), the Examiner still did not demonstrate that there would be any serious burden in examining at least Groups II, III, and IV together. Therefore, strictly in the alternative, at least Groups II, III, and IV should be rejoined.

The Examiner has not established distinctness of the Groups.

The Examiner did not establish that Group I is distinct from any of the other Groups. It was therefore improper to require restriction between Group I and any other Group. All other Groups should therefore be rejoined to Group I. I.e., the restriction requirement should be withdrawn in its entirety.

In each case, the Examiner asserted that the "method" of Group II, III, IV, or V might be practiced with a materially different product. However, the Examiner failed to make any showing that would support this contention.

Although the Examiner was wrong in each case, the proffered rationales were wrong for two different reasons: The Examiner was wrong for one reason in the case of Groups II, III, and IV; and wrong for a different reason in the case of Group V.

The Claims of Group I are drawn to DNA sequences. The Claims of Groups II, III, and IV are drawn to methods of using those DNA sequences. Relying on M.P.E.P. § 806.05(h), the Examiner asserted that the method claims of each of Groups II, III, and IV were distinct from the product claims of Group I, because the processes as claimed might be practiced with another, materially different product.

It is worth emphasizing that M.P.E.P. § 806.05(h) refers to practicing the process ***as claimed*** with a materially different product. (emphasis added) It is irrelevant that an Examiner might identify the possible existence of another, alternative method to achieve a similar goal, if the proposed alternative method lies outside the process ***as claimed***.

The Examiner's asserted "alternatives" are not, in fact, examples of the processes ***as claimed***. The proposed alternatives do not employ the DNA sequences that are expressly required by the limitations of Groups II, III, and IV. The Examiner's proposed alternatives describe different methods altogether, and are irrelevant for restriction purposes.

Regarding Group II, the Examiner asserted that estrogen might be used. (May 31, 2006 Office Action, p. 2, last par.)

Regarding Group III, the Examiner asserted that a growth inhibitor agent might be used. (May 31, 2006 Office Action, p. 3, first par.)

Regarding Group IV, the Examiner asserted that an antisense might be used. (May 31, 2006 Office Action, p. 3, second par.)

M.P.E.P. § 806.05(h) requires that the Examiner show that "the process of using ***as claimed*** can be practiced with another materially different product . . . ." (emphasis added).

However, the alternative methods cited by the Examiner for Groups II, III, and IV are not examples of the process ***as claimed***. Instead, they are examples of different processes entirely. They do not employ the DNA sequences that are required by the Claims of Groups II, III, and IV.

Group II will be used as an example to illustrate this point. The same basic argument applies to Groups III and IV as well. Separate explanations for Groups III and IV will be omitted in the interest of brevity:

The Examiner has not shown that Group II is distinct from Group I. Claim 31 is the independent Claim in Group II. Claim 31 reads:

> **31.** A method for decreasing fertility in an animal, comprising ***administering*** to the animal an effective amount of ***a DNA sequence*** encoding a peptide, wherein said peptide comprises a first domain and a second domain; wherein said first domain comprises a hormone selected from the group consisting of gonadotropin-releasing hormone, lamprey III luteinizing hormone releasing hormone (I-LHRH-III), the beta subunit of chorionic gonadotropin, the beta chain of luteinizing hormone (bLH), and analogs of these hormones; and wherein said second domain comprises a lytic peptide; wherein the lytic peptide comprises from 10 to 39 amino acid residues, is basic, and will form an amphipathic alpha helix.

(emphasis added)

Note that Claim 31 requires "***administering*** to the animal an effective amount of ***a DNA sequence*** . . ." (emphasis added)

The Examiner's proposed alternative was: "In the instant case the ***estrogen*** can be used in a method for decreasing fertility in an animal." (May 31, 2006 Restriction Requirement, p. 2, last paragraph). (emphasis added)

The Examiner did not satisfy the burden of showing that the process ***as claimed*** might be practiced with another, materially different product. Estrogen is a steroid, not a DNA sequence as required by independent Claim 31. At most, the Examiner has shown that there might exist a different process, using a different product, for achieving a similar

goal. However, the possible existence of alternative means to a similar end is simply irrelevant in analyzing the propriety of a restriction requirement, if the proposed alternative process is not in fact an alternative method for practicing the process ***as claimed***.

The same basic argument applies to Groups III and IV, for essentially the same reasons. The Examiner's proposed processes are simply not alternative methods for practicing the processes ***as claimed***. They involve different processes altogether, and do not employ the required DNA sequences. The Examiner has not shown that Group III is distinct from Group I, nor that Group IV is distinct from Group I.

The Examiner made a different error respecting Group V. The Examiner asserted that "Inventions I and V are related as product and process of use." (May 31, 2006 Restriction Requirement, p. 3) The Examiner's statement was clearly incorrect. Each Claim in Group V is directed to a product. No Claim in Group V is directed to a process. The Examiner's argument concerning an alleged alternative process is therefore misplaced. The Examiner has made no showing that Group V is distinct from Group I.

In summary, the Examiner has not carried the burden of showing that Group I is distinct from any of Groups II, III, IV, and V. The restriction requirement should be withdrawn for that reason alone.

IV. IN THE ALTERNATIVE, THE EXAMINER HAS NOT SHOWN THAT THERE WOULD BE A SERIOUS BURDEN IF RESTRICTION WERE NOT REQUIRED AMONG GROUPS II, III, AND IV.

The following argument respecting Groups II, III, and IV is presented in the alternative. Even if, for the sake of argument, one disagreed with the above reasons why

Group I should not be restricted from any of the other Groups, it would still be the case that the Examiner would not have justified restriction among Groups II, III, and IV.

In order to justify a restriction requirement, in addition to establishing independence or distinctness (which the Examiner has not done), the Examiner must also show that there would be a serious burden on the Examiner if restriction were not required. The Examiner has made no such showing as among Groups II, III, and IV. M.P.E.P. § 803 states: "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02."

Even if the Examiner had shown that the Groups were distinct from one another (and for the reasons given above, the Examiner has not done so), restriction still would not be justified among Groups II, III, and IV. The Examiner has not shown that there would be a serious burden in examining those Groups together.

The Examiner acknowledged that Groups II, III, and IV are identically classified, namely, in class 514, subclass 12. (May 31, 2006 Office Action, p. 2). Thus the Examiner has acknowledged that there would be no serious burden in examining Groups II, III, and IV together. Therefore, strictly in the alternative, at least the restriction requirement among Groups II, III, and IV should be withdrawn.

V. THE EXAMINER HAS NOT REPLIED TO APPLICANTS' ARGUMENTS IN A MEANINGFUL WAY.

In their July 5, 2006 Response to Restriction Requirement, the Applicants presented to the Examiner essentially the same arguments as those given above. The Examiner's subsequent response (August 18, 2006 Office Action, p. 2) offered no meaningful reply to the Applicants' arguments.

M.P.E.P. § 821.01, first paragraph, states that if the Examiner makes a restriction requirement final, then "the examiner should reply to the reasons or arguments advanced by applicant in the traverse." The Examiner has not done so.

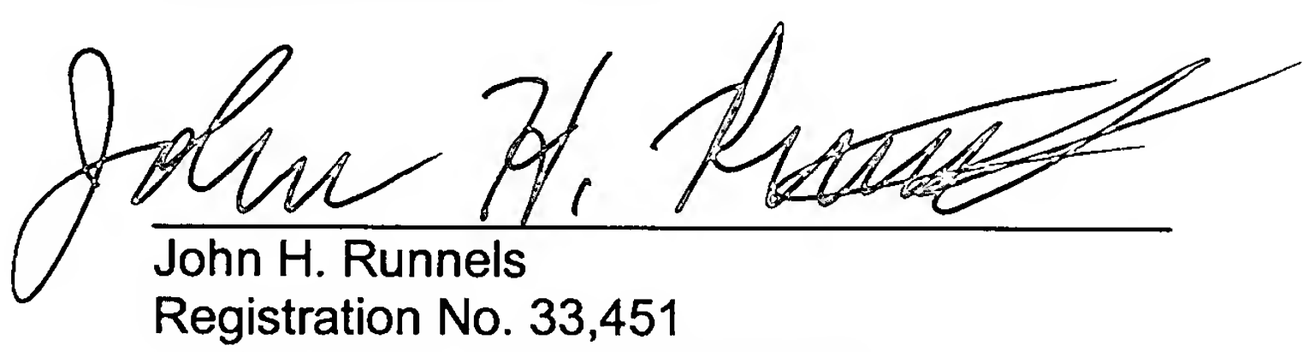
VI. THE AUGUST 18, 2006 OFFICE ACTION SHOULD BE WITHDRAWN, AND A NEW OFFICE ACTION SHOULD NOW BE MAILED.

Applicants recognize that the filing of the present Petition does not, in itself, extend the time for reply to the August 18, 2006 Office Action. However, this Petition is being filed promptly after the August 18, 2006 Office Action. If the present Petition should be granted before Applicants have submitted a reply to the merits of the August 18, 2006 Office Action, then in the interest of prosecution efficiency it is respectfully submitted that the August 18, 2006 Office Action should be withdrawn, and that a new Office Action should be mailed, setting a new period for response.

VII. CONCLUSION

Withdrawal of the restriction requirement is respectfully requested. Withdrawal of the finality of the August 18, 2006 Office Action is respectfully requested. It is respectfully requested that a new Office Action should be mailed, one that examines all pending Claims on the merits.

Respectfully submitted,



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